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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2009-0813; FRL-9363-6]

Glufosinate ammonium; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of glufosinate ammonium in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project Number 4 (IR-4) and Bayer CropScience requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective [*insert date of publication in the* **Federal Register**] except for the addition of the tolerance for Fruit, stone, group 12-12 to the table in § 180.473 (a), which is effective October 22, 2012. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the* **Federal Register**], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2009-0813, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the

telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-7610; email address: jackson.sidney@*epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2009-0813 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the* **Federal Register**]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2009-0813, by one of the following methods:

• *Federal eRulemaking Portal*: *http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm*.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets*.

II. Summary of Petitioned-For Tolerance

In the **Federal Registers** of January 6, 2010 (75 FR 864) (FRL-8801-5) and March 19, 2010 (75 FR 13277) (FRL-8813-2), EPA issued notices pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions; (PP 9E7604) by Interregional Research Project Number 4 (IR-4), IR-4 Project Headquarters, 500 College Road East, Suite 201 W, Princeton, NJ 08540 and (PP 9F7655) by Bayer CropScience LP, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709, respectively. The petitions requested that 40 CFR 180.473 be amended by establishing tolerances for residues of the herbicide glufosinate ammonium, butanoic acid , 2-amino-4-(hydroxymethylphosphinyl)- monoammonium salt, and its metabolites, 2-acetylamino-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, calculated as the stoichiometric equivalent of 2-amino-4-(hydroxymethylphosphinyl), in or on corn, sweet, forage at 4.0 parts per million (ppm); corn, sweet, kernel plus cob with husks removed at 0.2 ppm; corn, sweet, stover at 6.0 ppm (PP 9E7604); citrus, fruit (crop group 10) at 0.05 ppm; olives at 0.05 ppm; pome, fruit (crop group 11) at 0.10 ppm; and stone fruit (crop group 12) at 0.10 ppm (PP 9F7655). These notices referenced a

summary of the petition prepared by Bayer CropScience LP, 2 T. W. Alexander Drive, Research Triangle Park, NC 27709, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notices of filing.

Based upon review of the data supporting the petition, EPA is: (1) Correcting certain crop definitions to comply with current Agency policies; (2) establishing tolerance levels for certain commodities other than the proposed levels; (3) removing the proposed tolerance for plum, prune, dried; (4) modifying the crop group tolerances requested to the revised and expanded citrus fruit group 10-10, pome fruit group 11-10 and stone fruit group 12-12; and 5) revising the tolerance expression for all established commodities to be consistent with current Agency policy. The reasons for these changes are explained in Unit IV. C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a

reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D)**,** EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for glufosinate ammonium including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with glufosinate ammonium follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Technical grade glufosinate ammonium has low toxicity in the oral, dermal, inhalation studies and is not an eye or dermal irritant or a dermal sensitizer.

Subchronic toxicity studies in rats showed inhibition of glutamate synthetase and lead the Agency to conclude that the changes in brain glutamine synthetase activity are of significant concern for possible neurotoxicity and/or expression of clinical signs. Observed alterations in liver and kidney glutamate synthetase are considered an adaptive response. The primary effects in the mouse subchronic study were increased liver and kidney weights with increases in serum aspartate amino transferase and alkaline phosphatase.

Additional toxicity testing was conducted with the L-isomer of glufosinate ammonium, and degradates glufosinate propanoic acid (MPP), and 2-acetamido-4-methylphosphinico-butanoic acid (NAG). These compounds, tested in subchronic rat, mouse, and dog studies, and in developmental toxicity studies in rat and rabbit, are generally less toxic than the parent compound. However, L-isomer of glufosinate ammonium was found to be slightly more toxic than the racemic parent compound. This finding is not concern since this isomer is included in the toxicity testing of the parent compound at the levels in the technical material.

In chronic studies in the rat, inhibition of brain glutamine synthetase, increased mortality, and increased occurrence of retinal atrophy were noted, as were increased liver and kidney weights. In the mouse, increased mortality was noted, as were changes in glucose levels consistent with changes in glutathione levels. Increased mortality and electrocardiogram alterations were observed in dogs. The developmental toxicity study in the rat produced dilated renal pelvis and/or hydroureter in the fetuses at levels that produced significant increases in hyperactivity and vaginal bleeding in dams. In the rabbit, decreased fetal body weight and increased mortality were observed at 20 milligrams/kilogram/day (mg/kg/day), while in rabbit dams, decreased food consumption, body weight, and body weight gain were observed at 20 mg/kg/day. Since increased fetal mortality was observed in the presence of less severe maternal toxicity in the rabbit developmental study, there is evidence of *qualitative* increased susceptibility in fetuses.

The reproductive toxicity study in rats indicated postnatal developmental toxicity at the highest dose tested in the form of decrease in viable pups. No parental toxicity was

seen at the highest dose tested. Since pup mortality was observed in the absence of parental toxicity, there is evidence of *quantitative* increased susceptibility in offspring.

There were indications of neurotoxicity in several studies. Of particular concern is that the developmental neurotoxicity study demonstrated alterations in brain morphometrics in the adult offspring exposed *in utero* or during lactation at dose levels not associated with maternal toxicity. Retinal atrophy was observed in a rat oral study. In the 90-day dietary neurotoxicity study, increases in the incidence of decreased exploratory activity, decreased alertness, and decreased startle response, increased incidence of fearfulness, increased pain response and meiosis were reported. The subchronic dermal toxicity study indicated aggressive behavior, a high startle response and piloerection. The 28-day subchronic inhalation study demonstrated tono-clonic convulsions at the high dose in at least some males. However, in a 37-day dietary neurotoxicity study, there was no evidence of neurotoxicity at doses up to 143.3 mg/kg/day. There was no evidence of neurotoxicity in two acute neurotoxicity studies at doses up to 500 mg/kg/day. Also, there was no evidence of neurotoxicity in White Leghorn hens following an acute dose of up to 10,000 mg/kg. Changes in glutamine synthetase levels were observed in liver, kidney, and brain in rats. The altered electrocardiograms seen in the dog studies imply a possible neuromuscular effect.

There is no concern for immunotoxicity based on an adequate database.

There is no concern for mutagenic activity in several available studies including: Salmonella E. Coli, *in vitro* mammalian cell gene mutation assays, mammalian cell chromosome aberration assays, *in vivo* mouse bone marrow micronucleus assays, and unscheduled DNA synthesis assays.

Glufosinate ammonium was classified as "not likely to be a human carcinogen." There was no evidence of a treatment-related increase in tumors in either rats or mice.

Specific information on the studies received and the nature of the adverse effects caused by glufosinate ammonium as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at http://*www.regulations.gov* in document "Glufosinate Ammonium. Updated Human Health Risk Assessment for the Proposed New Use of Glufosinate Ammonium in/on Citrus Fruit (Crop Group 10), Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), Olives and Sweet Corn", dated July 25, 2012 at page number 34 in docket ID number EPA-HQ-OPP-2009-0813.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of

the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for glufosinate ammonium used for human risk assessment is shown in the following Table.

Table --Summary of Toxicological Doses and Endpoints for Glufosinate Ammonium for Use in Human Health Risk Assessment

Exposure/Scenario	**Point of Departure and Uncertainty/Safety Factors**	**RfD, PAD, LOC for Risk Assessment**	**Study and Toxicological Effects**
Acute Dietary (General Population, including Infants and Children)	No endpoint attributable to a single exposure was identified for the general population, including infants and children		
Acute dietary (Females 13-50 years of age)	NOAEL = 6.3 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	aRfD = 0.063 mg/kg/day aPAD = 0.063 mg/kg/day	Developmental Toxicity Study in Rabbits. LOAEL = 20 mg/kg/day based on increased fetal deaths.
Chronic dietary (All populations)	NOAEL = 6 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = UF_L = 10x	cRfD = cPAD = 0.006 mg/kg/day	"Weight of evidence" approach from four studies. Rat subchronic and chronic studies with the LOAEL based on inhibition of brain glutamate synthetase. A dog chronic study with the LOAEL based on altered electrocardiogram and mortality. The rat developmental neurotoxicity study with a LOAEL (without a

			NOAEL, basis for UF_L) based on altered morphometrics in the offspring as adults.
Dermal short-term (1 to 30 days)	LOAEL= 14 mg/kg/day (LDT) UF_A=10x UF_H=10x FQPA SF= UF_L= 10x	LOC for MOE = 1,000	Developmental Neurotoxicity Study in Rats LOAEL = 14 mg/kg/day based on brain morphometric changes at PND 72. No NOAEL identified.
Cancer (Oral, dermal, inhalation)	Classification: "Not likely to be Carcinogenic to Humans" based on the absence of significant tumor increases in two adequate rodent carcinogenicity studies.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies).. UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. In evaluating dietary exposure to glufosinate ammonium, EPA considered exposure under the petitioned-for tolerances as well as all existing glufosinate ammonium tolerances in 40 CFR 180.473. EPA assessed dietary exposures from glufosinate ammonium in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

Such effects were identified for glufosinate ammonium for females 13 through 50 years old. In estimating acute dietary exposure assessment of glufosinate ammonium, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 3.10, which incorporates consumption data

from USDA's National Health and Nutrition Examination Survey/"What We Eat in America" (NHANES/WWEIA) dietary survey conducted in 2003-2008. The 2003-2008 data are based on the reported consumption of individuals over two non-consecutive survey days.

As to residue levels in food, EPA assumed tolerance level residues for all established and recommended tolerances along with default processing factors, and 100 percent crop treated (PCT) assumptions.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA also used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database DEEM-FCID™, Version 3.10.

As to residue levels in food, EPA used anticipated residues based on average residue levels from field trial studies. The DEEM default processing factors were used for all commodities except apple juice, pear juice, grape juice, and raisins, for which factors derived from the processing studies were used in the assessment. One hundred percent crop treated values were used for all proposed new uses and some registered uses. Average PCT estimates were used in the chronic dietary analysis for crops that are currently registered for glufosinate ammonium if available.

iii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that glufosinate ammonium does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information*. Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide

residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) of FFDCA states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if:

• Condition a: The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.

• Condition b: The exposure estimate does not underestimate exposure for any significant subpopulation group.

• Condition c: Data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area.

In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency estimated the average PCT for existing uses as follows: almond: 15%; blueberry: 5%; field corn, 5%; grape, 15%; pecan, 1%; potato, 10%; soybean, 1%; walnut, 10%; canola, 25%; cotton, 5%; filbert, 10%; pistachio, 20%; and rice, 1%.

In most cases, EPA uses available data from United States Department of Agriculture/National Agricultural Statistics Service (USDA/NASS), proprietary market surveys, and the National Pesticide Use Database for the chemical/crop combination for the most recent 6-7 years. EPA uses an average PCT for chronic dietary risk analysis. The average PCT figure for each existing use is derived by combining available public and private market survey data for that use, averaging across all observations, and rounding to the nearest 5%, except for those situations in which the average PCT is less than one. In those cases, 1% is used as the average PCT and 2.5% is used as the maximum PCT. EPA uses a maximum PCT for acute dietary risk analysis. The maximum PCT figure is the highest observed maximum value reported within the recent 6 years of available public and private market survey data for the existing use and rounded up to the nearest multiple of 5%.

The Agency believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the

Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which glufosinate ammonium may be applied in a particular area.

2. *Dietary exposure from drinking water*. The Agency used refined drinking water exposure models in the dietary exposure analysis and risk assessment for glufosinate ammonium. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of glufosinate ammonium. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefed1/models/water/index.htm*.

Environmental fate studies indicate glufosinate ammonium is relatively stable and is very mobile. The main degradation pathway in water and soil is via microbial action, metabolizing primarily to CO_2, glufosinate propanoic acid (MPP), 2-methylphosphinico acetic acid (MPA), and 2-acetamido-4-methylphosphinico-butanoic acid (NAG). EPA recently reconsidered the appropriate residues of concern for drinking water to be used in risk assessment and determined that only the parent, glufosinate ammonium is the residue of concern for drinking water. Though MPA is a major degradate in some studies, a 90-day rat feeding study showed no effects at the highest dose tested which is about 100-fold higher than the NOAEL of the parent. Based on the rabbit developmental studies NAG is considered slightly less toxic than the parent. However, it was only observed as a major degradate during photolysis in soil; therefore, its exposure is significantly lower to that of the parent in drinking water. The parent glufosinate ammonium and MPP show different toxicities and therefore should not be aggregated. Moreover, the Agency has determined that the acute concentrations of MPP are not likely to be significantly greater than that of

glufosinate in drinking water. However, given the minimal fate data available for MPP that indicates MPP does not degrade in aerobic aquatic environments, it is unclear if this will be true for chronic concentrations of MPP and glufosinate. Since MPP is considered less toxic than the parent compound and should not be aggregated with the parent, EPA concluded that if estimated drinking water concentrations (EDWCs) of MPP are not significantly greater than those for glufosinate, the risk assessment for the parent will be protective of any toxicity associated with exposure to MPP in drinking water.

Previous analyses for glufosinate ammonium demonstrated that the maximum acute and chronic EDWCs result from surface water estimates arising from the rice use; the surface water values for rice are nearly an order of magnitude higher than any surface or ground water values for any other use of glufosinate ammonium. Therefore, a comprehensive refinement of the drinking water assessment for the rice use of glufosinate ammonium, should be protective of other uses.

The Agency estimated acute EDWCs for glufosinate ammonium and MPP using the Tier I Rice Model and Pesticide Flooded Application Model (PFAM) [version 0.70] without the index reservoir. To estimate chronic EDWCs, the acute concentrations from PFAM without the index reservoir were assumed to degrade over a 365-day period, using aerobic aquatic degradation half-lives; thus allowing calculation of average concentrations over a one-year period. This method results in chronic values approximately 76% and 3% lower than the acute values for glufosinate-ammonium and MPP, respectively.

The EDWCs for surface water are expected to be 390 parts per billion (ppb) for glufosinate and 183 ppb for MPP for acute exposures. The EDWCs for surface water are

expected to be 95 ppb for glufosinate and 177 ppb for MPP for chronic exposures. The maximum chronic EDWC for rice for MPP is approximately 2x higher than the corresponding value for glufosinate: 177 and 95 ppb, respectively. Since MPP is considered less toxic than the parent compound and should not be aggregated with the parent, EPA concluded that if the EDWCs for MPP are not significantly greater than those for glufosinate, the risk assessment for the parent will be protective of any toxicity associated with exposure to MPP in drinking water. Given the estimated EDWCs for MPP concentrations are not likely to be more than twice the corresponding levels of glufosinate in drinking water EPA concluded a quantitative risk assessment for MPP in drinking water is not needed. Accordingly, for purposes of acute and chronic dietary analyses, the recommended glufosinate EDWCs are 390 and 95 ppb, respectively.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 390 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 95 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Glufosinate ammonium is currently registered for the following uses that could result in residential exposures: spot treatments of lawns and turf. EPA assessed residential exposure using the following assumptions:

Residential handler exposure is expected to be short-term. Intermediate-term exposures are not likely because of the intermittent nature of applications by homeowners. Dermal and inhalation exposures are possible for applications from mixing/loading/applying liquids with a hose-end sprayer, a backpack sprayer, and a sprinkler can and applications for manually pressurized handgun. However, only the dermal route of exposure was included in the aggregate analysis since potential dermal risks are higher than potential inhalation risks and the EPA determined it is not appropriate to aggregate the dermal and inhalation exposures since the toxicity endpoints are different.

The Agency did not quantify post-application exposures. Post-application exposure is expected to be minimal. Any exposure to children via incidental non-dietary ingestion (i.e., hand-to-mouth, object-to-mouth (turfgrass), and soil ingestion) after application to treated turf is expected to be low since treatments to lawns and turf are limited to spot treatments.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at *http://www.epa.gov/pesticides/trac/science/trac6a05.pdf*.

4. *Cumulative effects from substances with a common mechanism of toxicity*. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA has not found glufosinate ammonium to share a common mechanism of toxicity with any other substances, and glufosinate ammonium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that glufosinate ammonium does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *http://www.epa.gov/pesticides/cumulative*.

D. Safety Factor for Infants and Children

1. *In general*. Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The reproductive toxicity study in rats indicated postnatal developmental toxicity at the highest dose tested in the form of decrease in viable pups. No parental toxicity was seen at the highest dose tested. Since pup mortality was observed in the absence of parental toxicity, there is evidence of *quantitative* increased susceptibility in offspring. Although in the rat developmental toxicity study dilated renal pelvis and hydroureter were observed in fetuses at 250

mg/kg/day, significant toxicity in the dams occurred at lower doses (vaginal bleeding and hyperactivity in the dams at 50 mg/kg/day), doses at which no developmental effects were observed. Therefore, no increased sensitivity was seen in this study.

Since increased fetal mortality was observed in the presence of less significant maternal toxicity in the rabbit developmental study, there is evidence of *qualitative* increased susceptibility in fetuses. Finally, the developmental neurotoxicity study demonstrated alterations in brain morphometrics in the adult offspring exposed *in utero* or during lactation at dose levels not associated with maternal toxicity. This shows quantitative sensitivity in the young.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA safety factor were reduced to 1X for acute dietary exposure. For all other exposure scenarios where the developmental neurotoxicity study or the 28-day inhalation study is used as an endpoint for risk assessment, EPA is retaining a 10X FQPA safety factor. That decision is based on the following findings:

i. Although all required studies for glufosinate ammonium have been submitted, the glufosinate ammonium database has a completeness issue in that the developmental neurotoxicity and the 28-day inhalation studies used for risk assessment did not demonstrate NOAELs, and LOAELs were used as endpoints. Therefore, the 10X FQPA safety factor was retained for use of a LOAEL to extrapolate a NOAEL. EPA has reduced the 10X safety factor when relying on a LOAEL in circumstances that suggest that the LOAEL is approaching a NOAEL (*e.g.*, very minimal effects seen at the

LOAEL). EPA, however has no reliable data supporting selection of a different safety factor value other than the default value of 10X for glufosinate ammonium.

ii. Although there were indications of neurotoxicity in several studies, the PODs and safety factors chosen for risk assessment are protective for these effects. The developmental neurotoxicity study showed altered brain morphometrics at the LOAEL, and this study is used in the weight-of-the evidence decision-making process for selection of an endpoint. Applying the 10X FQPA Safety Factor for the LOAEL to NOAEL extrapolation, as well as the 10X inter- and intra- species uncertainty factors, to this LOAEL will be protective against possible neurotoxicity as indicated in the laboratory animal studies.

iii. Although there is evidence that glufosinate ammonium results in increased qualitative or quantitative susceptibility in the developmental neurotoxicity study (rats), a prenatal developmental study (rabbits), and in the 2-generation reproduction study (rats), the PODs selected for risk assessment are protective for these effects because they are either based on clear NOAELs for the effects in young animals or they are based on a LOAEL adjusted by a 10X safety factor to account for the lack of a NOAEL in that study.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues. The chronic dietary exposure analysis was performed using anticipated residues from field trial data, processing factors and PCT information. With limited monitoring data available, upper-bound assumptions were used to determine exposure through drinking water sources. EPA made conservative (protective) assumptions in the

ground and surface water modeling used to assess exposure to glufosinate ammonium in drinking water. These assessments will not underestimate the exposure and risks posed by glufosinate ammonium.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to glufosinate ammonium will occupy 39% of the aPAD for females 13-49 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to glufosinate ammonium from food and water will utilize 98 % of the cPAD for all infants (<1 year old) the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of glufosinate ammonium is not expected.

3. *Short-term risk*. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

Glufosinate ammonium is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to glufosinate ammonium.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 1,800 for the general population for mixer/loader/applicators. Because EPA's level of concern for glufosinate ammonium is an MOE of 1,000 or below, these MOEs are not of concern.

4. *Intermediate-term risk*. Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level).

An intermediate-term adverse effect was identified; however, glufosinate ammonium is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for glufosinate ammonium**.**

5. *Aggregate cancer risk for U.S. population*. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, glufosinate ammonium is not expected to pose a cancer risk to humans.

6. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to glufosinate ammonium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Two analytical methods have been validated by EPA for enforcement of the currently established tolerances: (1) Method HRAV-5A for the determination of glufosinate ammonium and glufosinate propanoic acid in/on apple, grape, almond, soybean seed, corn grain, and corn forage, and (2) Method BK/01/99 for determination of glufosinate ammonium, *N*-acetyl-glufosinate, and glufosinate propanoic acid in/on canola seed and sugar beet root.

Based on the similarity in the two methods and the results from the petition method validations (PMVs), EPA concludes that method BK/01/99 is a suitable method for enforcement of sweet corn, stone fruit, pome fruit, citrus fruit and olive tolerances.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and

agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established MRLs for glufosinate ammonium in or on olives and sweet corn commodities. However, for glufosinate ammonium in or on citrus fruit, pome fruit and stone fruit, Codex has set MRLs of 0.1, 0.05, and 0.05 ppm, respectively. EPA is establishing tolerances in this action for citrus fruit, pome fruit, and stone fruit, at 0.15, 0.25 and 0.25 ppm, respectively. EPA cannot harmonize these tolerance values with the Codex MRLs because the lower MRLs could be exceeded with the uses petitioned-for in this action.

C. Revisions to Petitioned-For Tolerances

EPA modified/revised certain IR-4 proposed tolerances for glufosinate ammonium residues. Higher tolerance levels were established for citrus, pome fruit, stone fruit, and olives because EPA concluded that it was appropriate to sum the full level of quantification (LOQ) for each of the three residues of concern in situations where <LOQ residue levels were found. Sweet corn tolerances were amended based on results from the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedures the corn, sweet, K+CWHR tolerance proposed at 0.2 ppm will be

established at 0.30 ppm, corn, sweet, forage tolerance proposed at 4.0 ppm will be established at 1.5 ppm. A separate prune tolerance was established as residues in this processed commodity are covered by the stone fruit group tolerance.

Additionally, EPA was petitioned for tolerances on citrus fruit group 10, pome fruit group 11 and stone fruit group 12. In the **Federal Register** of December 8, 2010 (75 FR 76284) (FRL–8853–8) and Wednesday, August 22, 2012, EPA issued final rules that revised the crop grouping regulations. As part of those actions, EPA expanded and revised the existing citrus fruit group, pome fruit group and stone fruit group. The revised crop groups are designated as citrus fruit group 10-10, pome fruit group 11-10 and stone fruit group 12-12. As noted in the two crop group rulemakings, it is EPA policy to attempt to conform petitions for crop group tolerances filed prior the finalization of amendments to crop groups to the crop groups, as revised. This was possible in this case because the representative commodities for the crop groups did not change and the increased exposure as a result of the expanded crop groups could be assessed as part of review of the petition. Therefore, consistent with this policy, EPA has assessed and is establishing a tolerance on citrus fruit group 10-10, pome fruit group 11-10 and stone fruit group 12-12.

Finally, EPA has revised the tolerance expression to clarify (1) that, as provided in FFDCA section 408(a)(3), the tolerance covers metabolites and degradates of glufosinate ammonium not specifically mentioned; and (2) that compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

V. Conclusion

Therefore, tolerances are established for residues of glufosinate ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt) and its metabolites, 2-(acetylamino)-4-(hydroxymethyl phosphinyl) butanoic acid, and 3-(hydroxymethylphosphinyl) propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents in or on corn, sweet, forage at 1.5 ppm; corn, sweet, kernels plus cob with husks removed at 0.30 ppm; corn, sweet, stover at 6.0 ppm; fruit, citrus, group 10-10 at 0.15 ppm; fruit, pome, group 11-10 at 0.25 ppm; fruit, stone, group 12-12 at 0.25 ppm; and olive at 0.15 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq*.), nor does it require any special considerations under Executive Order 12898, entitled "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations" (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq*.), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled "Federalism" (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled "Consultation and Coordination with Indian Tribal Governments" (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq*.).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 19, 2012.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticides Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.473 is amended as follows:

i. Revise the introductory text in paragraphs (a) and (d).

ii. Add alphabetically the following commodities to the table in paragraph (a).

The revised and added text reads as follows:

§ 180.473 Glufosinate ammonium; tolerances for residues.

(a) *General.* Tolerances are established for residues of the herbicide glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring the sum of glufosinate ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt, and its metabolites, 2-(acetylamino)-4-(hydroxymethyl phosphinyl)butanoic acid, and 3-(hydroxymethylphosphinyl) propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents:

Commodity	Parts per million
* * *	* *
Corn, sweet, forage	1.5
Corn, sweet, kernels plus cob with husks removed	0.30
Corn, sweet, stover	6.0
* * *	* *
Fruit, citrus, group 10-10	0.15
Fruit, pome, group 11-10	0.25
Fruit, stone, group 12-12	0.25
* * *	* *
Olive	0.15
* * *	* *

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for indirect or inadvertent residues of glufosinate ammonium, including its metabolites and degradates, in or on the commodities in the table below, as a result of the application of glufosinate ammonium to crops listed in paragraph (a) of this section. Compliance with the tolerance levels specified below is to be determined by measuring the sum of glufosinate ammonium, butanoic acid, 2-amino-4-(hydroxymethylphosphinyl) monoammonium salt, and its metabolite, 3-(hydroxymethylphosphinyl)propanoic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl)butanoic acid equivalents.

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[FR Doc. 2012-23738 Filed 09/25/2012 at 8:45 am; Publication Date: 09/26/2012]